

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of: } Before the Examiner
Cesare Gianturco } Dalton Truluck
Serial No. 244,669 } Group Art Unit 336
Filed September 14, 1988 }
ENDOVASCULAR STENT AND }
DELIVERY SYSTEM }

DECLARATION OF DR. KENNETH WRIGHT

I, Kenneth Wright, hereby state as follows:

1. I am currently engaged in ~~experimental medicine~~^{XCW} and medical research at the University of Texas. Prior to November 7, 1985, I was also engaged in medical research, including research concerning vascular diseases.

2. Prior to November 7, 1985, Dr. Cesare Gianturco disclosed to me an implantable balloon-expanded stent comprised of a wire composed of a malleable metallic material wrapped around an angioplasty balloon in a U-inverted U fashion, or in a series of alternating clockwise and counterclockwise helical sections, to form an implantable stent.

3. Prior to November 7, 1985, I performed in vivo tests of the balloon-expanded stent described above at the direction and under the observation of Dr. Gianturco. During the in vivo tests, I inserted an angioplasty balloon with the wire stent engaged thereabout into the external iliac artery of a live dog. The balloon was inflated to expand the stent into contact with the artery wall, which was verified by radiograph of the implantation region. After it was determined by radiograph observation that the stent had been properly positioned in the artery, the

balloon was deflated. After verifying that the stent had been securely implanted in the artery wall, the balloon catheter was removed.

4. I inserted a second balloon catheter with a stent engaged thereabout into the other external iliac artery of the same dog. After the balloon catheter and stent had been inserted into the artery to the implantation site, radiography revealed that the stent had displaced slightly on the balloon catheter. The balloon was inflated to expand a portion of the stent into contact with and implanted in the artery wall. ^{WITHDRAWN Xcw} The balloon was then deflated and ~~advanced~~ into the unexpanded portion of the stent, wherein the balloon was re-inflated to expand the remaining portion of the stent.

5. Attached to this Declaration is a photocopy of a radiograph image taken ^{4 WEEKS AFTER Xcw} of the implantable balloon-expanded stent ~~during~~ the above described in vivo tests in both iliac arteries of the dog. I attest that this photocopy is a true and complete copy of the actual radiograph image and that this radiograph image is the actual and ^{4 WEEKS AFTER Xcw} authentic image obtained ~~during~~ the above described in vivo tests.

6. All statements made in this Declaration of my own knowledge are true, and all statements made on information and belief are believed to be true. This Declaration has been made and signed with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both (18 U.S.C. §1001) and may jeopardize the validity of this application or any patent issuing thereon.

Date: 12-19-88

Kenneth C. Wright
Kenneth Wright, M.D.
P.H.D. ^{Xcw}

